ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 11/30/2010

ClinicalTrials.gov ID: NCT00427960

Study Identification

Unique Protocol ID:	D3560L00060
Brief Title:	Study of Asian Patients With Hypercholesterolaemia in the UK - Rosuvastatin 5mg Versus Atorvastatin 10mg
Official Title:	A Phase IV, 6-week, Randomised, Double-blind, Multicentre, Parallel Group, Comparative Study to Evaluate the Efficacy of Rosuvastatin 5mg and Atorvastatin 10mg in UK Asian Subjects With Primary Hypercholesterolaemia
Secondary IDs:	SHUKRA

Study Status

Record Verification:	November 2010
Overall Status:	Terminated
Study Start:	December 2006
Primary Completion:	February 2008 [Actual]
Study Completion:	February 2008 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	
Collaborators:	

Oversight

FDA Regulated?:	
IND/IDE Protocol?:	No

Review Board:	Approval Status: Approved Approval Number: 06/Q1206/135 Board Name: Leeds (East) MREC Board Affiliation: COREC Phone: 0113 206 5637 Email: a.d.prothero@leeds.ac.uk
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study Description

Brief Summary:	The purpose of this study is to compare the effectiveness and safety of rosuvastatin 5mg in lowering blood cholesterol, compared to one other medicine, atorvastatin 10mg in Asian patients in the UK.
Detailed Description:	

Conditions

Conditions:	Hypercholesterolaemia
Keywords:	cholesterol statin Asian LDL-cholesterol

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind
Allocation:	Randomized
Endpoint Classification:	Efficacy Study
Enrollment:	55 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: rosuvastatin rosuvastatin 5 mg	Behavioral: Dietary advice Drug: rosuvastatin rosuvastatin 5 mg Other Names: • Crestor
Active Comparator: atorvastatin atorvastatin 10 mg	Behavioral: Dietary advice Drug: atorvastatin atorvastatin 10 mg

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Self described Asian, first or second generation
- Male or female > or = 18 years with primary hypercholesterolaemia.

Exclusion Criteria:

- Use of cholesterol lowering drugs from visit 1
- Homozygous familial hypercholesterolaemia
- Active arterial disease within 3 months of study entry
- Poorly controlled diabetes
- Uncontrolled hypothyroidism
- Active liver disease
- History of alcoh/drug abuse.

Contacts/Locations

Study Officials: Rhiannon Rowsell, MD

Study Director
AstraZeneca

Shahid Ali, MD
Study Principal Investigator
Bradford PCT

Locations: United Kingdom
Research Site
Blackburn, United Kingdom

Research Site
Crawley, United Kingdom

Research Site
Allerton, United Kingdom

Research Site
Birmingham, United Kingdom

Research Site
Bolton, United Kingdom

Research SIte
Glasgow, United Kingdom

Research Site
Newcastle, United Kingdom

Research SIte
Sheffield, United Kingdom

Research SIte
Slough, United Kingdom

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	Participants were recruited from 25 primary and secondary care centres in the United Kingdom. The first participant was enrolled on 20th December 2006 and the last participant entered the study on 16th November 2007.
Pre-Assignment Details	Participants entered an initial 6-week dietary run-in/ wash-out period, after which those with a fasting low density lipoprotein cholesterol (LDL-C) of greater than or equal to 4.00 mmol/L and triglycerides (TG) less than 4.52 mmol/L, were randomised to receive treatment with either rosuvastatin 5 mg plus atorvatstatin , or atorvastatin 10mg

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Overall Study

	Rosuvastatin	Atorvastatin
Started	30	25
Completed	28	21
Not Completed	2	4
Adverse Event	2	0
Withdrawal by Subject	0	3
Not Specified	0	1

Baseline Characteristics

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Baseline Measures

	Rosuvastatin	Atorvastatin	Total
Number of Participants	30	25	55
Age, Continuous [units: years] Mean (Standard Deviation)	50 (11)	53 (11)	51.5 (11)
Gender, Male/Female [units: participants]			
Female	13	11	24.0
Male	17	14	31.0

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage Change in Low Density Lipoprotein - Cholesterol (LDL-C)
Measure Description	Calculated as LDL-C at Week 6 - LDL-C at Week 12] * 100
Time Frame	6 weeks (baseline) and 12 weeks
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population (all randomized patients).

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Measured Values

	Rosuvastatin	Atorvastatin
Number of Participants Analyzed	30	25
Percentage Change in Low Density Lipoprotein - Cholesterol (LDL-C) [units: Percent Change in LDL-C]	33.28	36.92

2. Secondary Outcome Measure:

Measure Title	The Percentage of Participants Reaching the General Medical Services (GMS) Contract Target of Total Cholesterol (TC) <5 mmol/L
Measure Description	
Time Frame	6 weeks (Baseline) and 12 weeks
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population (all randomized patients).

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Measured Values

	Rosuvastatin	Atorvastatin
Number of Participants Analyzed	30	25
The Percentage of Participants Reaching the General Medical Services (GMS) Contract Target of Total Cholesterol (TC) <5 mmol/L [units: Percentage of Participants]	50	64

3. Secondary Outcome Measure:

Measure Title	The Percentage of Participants Reaching the Joint British Societies' Guideline (JBS 2) Targets of TC <4 mmol/L and LDL-C <2 mmol/L
Measure Description	
Time Frame	6 weeks (baseline) and 12 weeks
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population (all randomized patients).

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Measured Values

	Rosuvastatin	Atorvastatin
Number of Participants Analyzed	30	25
The Percentage of Participants Reaching the Joint British Societies' Guideline (JBS 2) Targets of TC <4 mmol/L and LDL-C <2 mmol/L [units: Percentage of Participants]	16	28

4. Secondary Outcome Measure:

Measure Title	The Percentage of Participants Reaching the European (EAS) Targets of LDL-C<2.5 or 3.00 mmol/L, Depending on Risk Category, and the Combined LDL-C and TC Target of LDL-C<2.5 or 3.0 mmol/L and TC<4.5 or 5.0 mmol/L, Both Depending on Risk Category.
Measure Description	Risk categories are: Symptomatic Asymptomatic, total risk <5% Asymptomatic, total risk ≥5%, baseline LDL-C<3 mmol/L and baseline TC<5 mmol/L Asymptomatic, total risk ≥5%, baseline LDL-C ≥3 mmol/L or baseline TC ≥5 mmol/L Patients are defined as symptomatic if they meet at least 1 of the following criteria: History of cardiovascular disease Type II diabetes or diabetes of unknown type Baseline TC ≥8 mmol/l Baseline LDL-C ≥6 mmol/l Baseline systolic BP ≥180 mmHg Baseline diastolic BP ≥110 mmHg Total risk is derived from age, sex, TC, systolic BP and smoking status.
Time Frame	6 weeks (baseline) and 12 weeks
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population (all randomized patients).

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg

	Description
Atorvastatin	atorvastatin 10 mg

Measured Values

	Rosuvastatin	Atorvastatin
Number of Participants Analyzed	30	25
The Percentage of Participants Reaching the European (EAS) Targets of LDL-C<2.5 or 3.00 mmol/L, Depending on Risk Category, and the Combined LDL-C and TC Target of LDL-C<2.5 or 3.0 mmol/L and TC<4.5 or 5.0 mmol/L, Both Depending on Risk Category. [units: Percentage of Participants]	43	48

5. Secondary Outcome Measure:

Measure Title	The Percentage Change From Baseline(week6) in TC
Measure Description	Derived according to the following formula: 100*[Lipid at week 12 - Lipid at week 6]/Lipid at week 6
Time Frame	6 weeks (baseline) and 12 weeks
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population (all randomized patients).

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Measured Values

	Rosuvastatin	Atorvastatin
Number of Participants Analyzed	30	25
The Percentage Change From Baseline(week6) in TC [units: Percent Change in TC]	-23.03	-26.88

6. Secondary Outcome Measure:

Measure Title	The Percentage Change From Baseline (Week 6) in High-density Lipoprotein Cholesterol (HDL-C)
Measure Description	Derived according to the following formula: 100*[Lipid at week 12 - Lipid at week 6]/Lipid at week 6
Time Frame	6 weeks (baseline) and 12 weeks
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population (all randomized patients).

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Measured Values

	Rosuvastatin	Atorvastatin
Number of Participants Analyzed	30	25
The Percentage Change From Baseline (Week 6) in High-density Lipoprotein Cholesterol (HDL-C) [units: Percent Change in HDL-C]	4.46	3.15

7. Secondary Outcome Measure:

Measure Title	The Percentage of Participants Reaching the Joint British Societies Guideline (JBS 2) Target of TC <4 mmol/L
Measure Description	
Time Frame	6 weeks (baseline) and 12 weeks
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population (all randomized patients).

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Measured Values

	Rosuvastatin	Atorvastatin
Number of Participants Analyzed	30	25
The Percentage of Participants Reaching the Joint British Societies Guideline (JBS 2) Target of TC <4 mmol/L [units: Percentage of Participants]	13	12

8. Secondary Outcome Measure:

Measure Title	The Percentage Change From Baseline (Week 6)in Non-HDL-C
Measure Description	Derived according to the following formula: 100*[Lipid at week 12 - Lipid at week 6]/Lipid at week 6
Time Frame	6 weeks (baseline) and 12 weeks
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population (all randomized patients).

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Measured Values

	Rosuvastatin	Atorvastatin
Number of Participants Analyzed	30	25
The Percentage Change From Baseline (Week 6)in Non-HDL-C [units: Percent Change in Non-HDL-C]	-29.72	-34.09

9. Secondary Outcome Measure:

Measure Title	The Percentage Change From Baseline (Week 6) in Apolipoprotein-B (ApoB)
Measure Description	Derived according to the following formula: 100*[Lipid at week 12 - Lipid at week 6]/Lipid at week 6
Time Frame	6 weeks (baseline) and 12 weeks
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population (all randomized patients).

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Measured Values

	Rosuvastatin	Atorvastatin
Number of Participants Analyzed	30	25
The Percentage Change From Baseline (Week 6) in Apolipoprotein-B (ApoB) [units: Percent Change in ApoB]	-25.96	-28.67

10. Secondary Outcome Measure:

Measure Title	The Percentage Change From Baseline (Week 6) in Apolipoprotein-A1 (ApoA1)
Measure Description	Derived according to the following formula: 100*[Lipid at week 12 - Lipid at week 6]/Lipid at week 6
Time Frame	6 weeks (baseline) and 12 weeks
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population (all randomized patients).

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Measured Values

	Rosuvastatin	Atorvastatin
Number of Participants Analyzed	30	25
The Percentage Change From Baseline (Week 6) in Apolipoprotein-A1 (ApoA1) [units: Percent Change in ApoA1]	-0.55	1.89

11. Secondary Outcome Measure:

Measure Title	The Percentage Change From Baseline (Week 6)in LDL-C/HDL-C Ratio
Measure Description	Derived according to the following formula: 100*[Lipid at week 12 - Lipid at week 6]/Lipid at week 6
Time Frame	6 weeks (baseline) and 12 weeks
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population (all randomized patients).

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Measured Values

	Rosuvastatin	Atorvastatin
Number of Participants Analyzed	30	25
The Percentage Change From Baseline (Week 6)in LDL-C/HDL-C Ratio [units: Percent Change in LDL-C/HDL-C Ratio]	-34.75	-38.45

12. Secondary Outcome Measure:

Measure Title	The Percentage Change From Baseline (Week 6) in TC/HDL-C Ratio
Measure Description	Derived according to the following formula: 100*[Lipid at week 12 - Lipid at week 6]/Lipid at week 6
Time Frame	6 weeks (baseline) and 12 weeks
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population (all randomized patients).

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Measured Values

	Rosuvastatin	Atorvastatin
Number of Participants Analyzed	30	25
The Percentage Change From Baseline (Week 6) in TC/HDL-C Ratio [units: Percent Change in TC/HDL-C Ratio]	-24.99	-28.42

13. Secondary Outcome Measure:

Measure Title	The Percentage Change From Baseline(Week 6) in Non-HDL-C/HDL-C Ratio
Measure Description	Derived according to the following formula: 100*[Lipid at week 12 - Lipid at week 6]/Lipid at week 6
Time Frame	6 weeks (baseline) and 12 weeks
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population (all randomized patients).

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Measured Values

	Rosuvastatin	Atorvastatin
Number of Participants Analyzed	30	25
The Percentage Change From Baseline(Week 6) in Non-HDL-C/HDL-C Ratio [units: Percent Change in Non-HDL-C/HDL-C Ratio]	-31.05	-35.48

14. Secondary Outcome Measure:

Measure Title	The Percentage Change From Baseline (Week 6) in ApoB/ApoA1 Ratio
Measure Description	Derived according to the following formula: 100*[Lipid at week 12 - Lipid at week 6]/Lipid at week 6
Time Frame	6 weeks (baseline) and 12 weeks
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population (all randomized patients).

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Measured Values

	Rosuvastatin	Atorvastatin
Number of Participants Analyzed	30	25
The Percentage Change From Baseline (Week 6) in ApoB/ApoA1 Ratio [units: Percent Change in ApoB/ApoA1 Ratio]	-22.89	-28.75

15. Secondary Outcome Measure:

Measure Title	The Percentage of Participants Reaching the European (EAS) Targets of LDL-C<2.5 or 3.00 mmol/L, Depending on Risk Category.
Measure Description	Risk categories are: Symptomatic Asymptomatic, total risk <5% Asymptomatic, total risk ≥5%, baseline LDL-C<3 mmol/L and baseline TC<5 mmol/L Asymptomatic, total risk ≥5%, baseline LDL-C ≥3 mmol/L or baseline TC ≥5 mmol/L Patients are defined as symptomatic if they meet at least 1 of the following criteria: History of cardiovascular disease Type II diabetes or diabetes of unknown type Baseline TC ≥8 mmol/l Baseline LDL-C ≥6 mmol/l Baseline systolic BP ≥180 mmHg Baseline diastolic BP ≥110 mmHg Total risk is derived from age, sex, TC, systolic BP and smoking status.
Time Frame	6 weeks (baseline) and 12 weeks
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population (all randomized patients).

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Measured Values

	Rosuvastatin	Atorvastatin
Number of Participants Analyzed	30	25
The Percentage of Participants Reaching the European (EAS) Targets of LDL-C<2.5 or 3.00 mmol/L, Depending on Risk Category. [units: Percentage of Participants]	56.7	56.0

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
Rosuvastatin	rosuvastatin 5 mg
Atorvastatin	atorvastatin 10 mg

Serious Adverse Events

	Rosuvastatin	Atorvastatin
	Affected/At Risk (%)	Affected/At Risk (%)
Total	1/	0/
Nervous system disorders		
Cerebrovascular Accident [A] †	1/30 (3.33%)	0/30 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 10.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Rosuvastatin	Atorvastatin
	Affected/At Risk (%)	Affected/At Risk (%)
Total	4/	3/
Nervous system disorders		
Dizziness [A] †	3/30 (10%)	1/25 (4%)
Headache [A] †	1/30 (3.33%)	2/25 (8%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 10.0

Limitations and Caveats

The study achieved only 8% of the randomised target number of patients and for this reason alone was terminated early. Planned statistical analyses could not be performed. No scientifically valid conclusions can be drawn from the limited study data.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Gerard Lynch
Organization: Astrazeneca
Phone:
Email: AZTrial_Results_Posting@astrazeneca.com